

REMARKS

Claims 20, 22-24, and 26-44 are pending in the present application. Claims 20, 22-24, and 26-44 are rejected. By this response, claims 20, 32, 41 and 44 have been amended. Accordingly, claims 20, 22-24, and 26-44 are currently under consideration.

With respect to claim amendments and cancellations, Applicants have not dedicated to the public or abandoned any unclaimed subject matter and have not acquiesced to any rejections and/or objections by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Reconsideration of the application is respectfully requested in view of the following remarks. For the Examiner's convenience, Applicants' remarks are presented in the order in which they were raised in the Office Action.

Applicants thank Examiner K. George for extending the courtesy of discussing issues and arguments made in this response.

A. Action Summary

Claim 20 is amended to recite "hollow, spray-dried" microparticles. Support for "spray-dried microparticles" can be found in the originally-filed application at page 1, lines 7-8. Support for "hollow" microparticles can be found in the originally-filed application at page 14, lines 25-27.

No new matter is added by the amendments, and entry of the amendments is respectfully requested.

B. Claim Rejections Under 35 U.S.C. § 103

Claims 20, 22-24, and 26-44 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Platz. et al. (US 6,509,006).

1. *Platz as prior art over the present application.*

Platz is cited as art over the present application as a result of its entitlement to the priority document of Ser. No. 07/910,048, filed Jul. 8, 1992 (issued as US pat. No. 5,458,135). Applicants submit that the entire disclosure of Platz cannot be considered as "prior" art, as the entire disclosure of Platz is not found in the '135 patent (filed Jul. 8, 1992).

In particular, the Examiner has cited columns 6-9 of Platz for disclosures related to limitations in the pending claims. The Examiner has cited Platz for disclosing: therapeutically effective amount of a pharmaceutical in combination with a pharmaceutically acceptable carrier (col. 5: lines 63-67); particle size of less than 10 microns (8:67 - 9:7); pharmaceutical is a protein, peptide or enzyme (6:1-13); carrier in amounts of 0.05% to 99.5% (6:27-34); carrier as an excipient and carbohydrate bulking agents (6:35 - 7:6); dry powder inhaler (7:27-56) and additives to improve dispersability (7:7-11). (Office Action, pages 3-4).

Applicants note that none of this disclosure found at columns 5-9 in Platz, can be found in the July 8, 1992 priority document, the '135 patent.

2. *Applicants' amendments and response to Examiner's arguments for prima facie obviousness*

The Examiner states that "although substantially non-denatured proteins peptides or enzymes are not explicitly taught by Platz *et al.* it can be inferred from the reference that it can be used." (Office Action, page 4). The Examiner further states that the amendment reciting that the microparticles are "produced by a process which is controlled to avoid denaturing of the protein, peptide or enzyme" does not overcome the prior art as it would have been obvious for a skilled artisan to avoid denaturing the protein, peptide or enzyme.

In response, Applicants amend independent claims 20, 32, 41 and 44 to delete the limitation of microparticles "produced by a process which is controlled to avoid denaturing of the protein, peptide or enzyme" and specify that the therapeutic composition comprises "hollow, spray-dried microparticles."

Platz *et al.* itself is not prior art over the instant application. The priority document that Platz is entitled to is US Patent No. 5,458,135 ("the '135 patent").

First, Applicants submit that the Platz priority document – the '135 patent – does not teach or suggest that spray-drying can be used to form therapeutic microparticles without denaturing sensitive materials such as proteins.

Second, Applicants submit that Platz does not disclose "hollow" microparticles as specified in the amended independent claims 20, 32, 41 and 44. Spray-drying does not necessarily produce "hollow" microparticles and Platz does not teach or suggest any method for controlling the production of microparticles such that they remain hollow.

Since Platz does not teach or suggest each and every limitation of the independent claims 20, 32, 41 and 44, as amended, a *prima facie* case for obviousness is not met and claims 22-24, and 26-31, 33-40, 42 and 43 depend from claims 20, 32, and 41. Therefore, Applicants respectfully request withdrawal of this ground for rejection for pending claims 20, 22-24, and 26-44.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to allow this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **263742002802**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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